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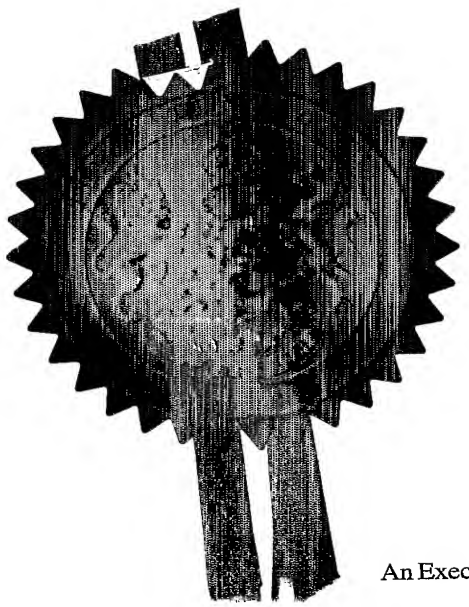

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3. Full name, address and postcode of the or of each applicant *(underline all surnames)*
Dialog Devices Limited,
Rutland Hall,
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Patents ADP number *(if you know it)*
8655359001

If the applicant is a corporate body, give the country/state of its incorporation
United Kingdom

4. Title of the invention
A system or method for assessing a subject's pedal blood circulation.

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*
Swindell & Pearson
48 Friar Gate
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Description	12
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Signature(s) Swindell & Pearson Date 07/01/04

12. Name, daytime telephone number and e-mail address, if any, of person to contact in the United Kingdom Paul Higgin - 01332 367051

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A system or method for assessing a subject's pedal blood circulation

Embodiments of the invention relate to assessing a subject's pedal blood circulation.

Healthy feet are an important factor in quality of life, independent living and personal freedom. Disorders of the vascular system can lead to unhealthy feet. This is a particular risk for people with diabetes. Diabetes can affect the feet in two key ways: nerve damage or "diabetic neuropathy" and narrowing of the blood vessels or "diabetic vasculopathy"

Diabetic neuropathy decreases pain sensation in the feet and results in an increased risk of infection and amputation. Diabetic vasculopathy is characterised by poor blood circulation and an insufficient supply of nutrients to maintain tissue health and to fight infections. This results in secondary deterioration of tissues (including bones) leading to pressure areas, skin breakdown, flattening of the foot etc.

There are a few clinic/GP based technologies that are used currently to assess a diabetic foot and Peripheral Vascular Disease. However, these technologies are generally interpretive and must be practised by a correctly trained person.

It would be desirable to provide for the objective assessment of lower limb perfusion.

According to one embodiment of the invention there is provided a system for assessing a subject's pedal blood circulation, comprising: measurement means for measuring a parameter dependent upon the blood volume in the subject's foot at a raised elevation and processing means for determining a quantitative blood perfusion indictor using the measured parameter.

According to another embodiment of the invention there is provided a method for assessing a subject's pedal blood circulation, comprising: measuring a parameter dependent upon the blood volume in the subject's foot at a raised elevation and determining a quantitative blood perfusion indictor using the measured parameter.

Embodiments of the invention therefore provide a quantitative blood diffusion indicator in a robust and quick manner at modest cost without discomfort to the user. Some embodiments may be automated,

For a better understanding of the present invention reference will now be made by way of example only to the accompanying drawings in which:

Fig. 1 schematically illustrates a system 10 for the objective assessment of blood perfusion in a lower limb 12 of a subject;

Fig. 2 illustrates a system 10 for the objective assessment of blood perfusion in a lower limb 12 of a subject using an optical sensor 4;

Fig. 3 schematically illustrates the components of the system illustrated in Fig. 2.

Figs. 4A and 4B illustrate the change in pulsatile perfusion for a healthy subject's leg when raised to 30 degrees; and

Figs. 5A and 5B illustrate the change in pulsatile perfusion for an at risk subject's leg when raised to 30 degrees.

The Figures illustrate a system 10 for assessing a subject's pedal blood circulation, comprising: measurement means 4 for measuring a parameter dependent upon the blood volume in the subject's foot at a raised elevation and processing means 5 for determining a quantitative blood perfusion indictor using the measured parameter.

The blood volume in a lower limb includes a variable volume, and a fixed volume. The variable blood volume arises from pulsating blood flow within the arteries of the lower limb and varies with a periodicity in the range 0.5-3Hz. The fixed volume includes the venous volume of blood and varies, if at all, over a time scale of several seconds.

The blood circulation system is governed in part by forces exerted by gravity. In order that a suitable blood flow is maintained throughout the body, the vascular system can adjust to any local pressure changes resulting from postural changes. Thus the resistance of the peripheral vascular system in the feet is high when a subject is standing compared with when they are supine. Although the relationships between pressure, flow and blood volume are complex, certain patterns can be identified that characterise the response of the circulation system to specific changes (e.g. postural changes). These patterns can be disrupted when a pathology is present such as an arterial blockage or a when the vasculature has a reduced capability to respond to changes imposed upon it. This is the principle of response testing which is exploited in this invention.

When a lower limb is raised above the heart, the circulation system will respond to the change in localised blood pressure in a manner characteristic of any pathology. This characteristic change is detected by measuring changes in the blood volume in the limb and/or changes to the skin tone.

Fig. 1 schematically illustrates a system 10 for the objective assessment of blood perfusion in a lower limb 12 of a subject. The system 10 automatically determines quantitative indicators of lower limb blood perfusion and provides these perfusion indicators and/or an assessment of the subject's risk of vascular disorders. One perfusion indicator is obtained by measuring the change in pedal arterial circulation volume in a lower limb 12 in response to its elevation H above the

subject's heart. Another indicator is obtained by measuring a change in the lower limb 12 flesh tone (colour) in response to its elevation H above the subject's heart.

The subject lies flat on their back, while a measurement is taken with the subject's lower limb 12 in a non-elevated position and a measurement is taken with the subject's lower limb 12 in an elevated position. Elevation is relative to the subject's heart reference level 3.

The system 10 comprises a lifting mechanism for raising a subject's leg 2 from the non-elevated position to the elevated position. The leg 2 pivots about the subject's hip 1. The mechanism may be a lifting pulley 7 or alternatively a lifting platform 6.

The system additionally comprises a blood volume sensor 4 and a control unit 5. The sensor 4 includes a support that fits around the lower limb 12, specifically around the ankle and dorsum of the foot. The sensor 4 may include a strain gauge wrapped around the dorsum or alternatively it may include a light source and light sensors to detect blood volume changes.

The control unit 5 receives a first input from the sensor when the foot has a first zero elevation above the subject's heart and a second input from the sensor when the foot has a second non-zero elevation above the subject's heart. The control unit 5 processes the first and second inputs to quantify the change in arterial blood volume with elevation. This may be used as a quantitative perfusion indicator that indicates the status of arterial blood circulation in the foot 12.

It may be desirable for the second input to be taken when the subject's foot 12 is at a particular elevation. The lifting mechanism may be calibrated to enable the foot to be manually elevated to the correct height. Alternatively, the lifting mechanism may provide a signal to the control unit 5, which automatically

controls the lifting mechanism to stop elevation at a desired height or provides an alert to an operator to stop elevating the foot at the required height.

Instead of using the lifting mechanism to measure the elevation, it is also possible to use the control unit 5 to estimate the elevation. In this case, an electronic inclinometer would be attached to the subject's lower limb with a correct orientation. It may, for example, be integrated into the sensor 4 or control unit 5. The inclinometer provides an incline input θ to the control unit 5 which uses a value of the subject's leg length L to estimate the elevation H of the lower limb 12 using trigonometry ($H = L * \tan \theta$). The leg length L may be input into the control unit 5 after direct measurement or may be estimated by the control unit 5 from a value of the subject's height input to the control unit 5. The control unit 4 may additionally either control the rate of change of elevation by controlling the lifting mechanism or may monitor the rate of change of elevation and provide an audio alert if the rate of elevation is too fast or too slow.

In the illustrated embodiment, the control unit 5 forms part of the sensor support 4, but in other embodiments it may be mounted on the sensor support and directly connected to it or it may be positioned remote from the sensor support 4 and indirectly connected to it e.g. using radio transceivers.

The control unit 5 may include a user interface including a user input device such as a keyboard and a user output device such as a display. The display may, for example, display the elevation of the lower limb 12, the equivalent hydrostatic pressure for that elevation, a first perfusion indicator dependent upon the pedal arterial circulation volume in the elevated lower limb 12 and a second perfusion indicator dependent upon the flesh tone (colour) of the elevated lower limb.

Fig. 2 illustrates a system 10 for the objective assessment of blood perfusion in a lower limb 12 of a subject using an optical sensor 4. The Figure illustrates a non-contact embodiment.

The system 10 comprises a photo-plethysmographic (PPG) 4 sensor, an electronic inclinometer (INC) 14, an optically diffusive skin (ODS) 16 and an electronic control unit (ECU) 5 that includes pre-processing circuitry 60 and an analysis unit (ANU) 56, which may be a microprocessor.

The PPG sensor 4 illuminates the dorsum of the foot from a range of a few cm. The PPG sensor 4 uses an array of light emitting diodes to provide a diffuse illumination pattern that extends over a significant fraction of the dorsum (approx. 20 sq cm). The optical receiver is located adjacent to the array of photodiodes or is mounted within the array. Light collection optics (reflectors or lenses) can be used to shape the beam pattern and collection aperture.

The optically diffusive skin (ODS) 16 covers the area of tissue to be illuminated (e.g. dorsum of the foot). The skin may, for example, be made from a polymer material such as latex. The skin 16 functions to reduce in-homogeneity in the optical interaction with the tissue by creating a smooth but diffusive interface between the illuminating light field and the actual skin surface.

The inclinometer 14 is aligned with the shinbone. The inclinometer 14 registers the angle θ at which the leg 2 is inclined. This value is converted to an elevation and hydrostatic pressure change by the electronic control unit 5. The leg length may be entered directly to the control unit 4 via or it may be derived from a look up table based on the subject's height.

The PPG sensor 4 produces an output voltage that is dependent upon the intensity of the light detected by the sensor. This output voltage is provided to the pre-processing circuitry 60 of the electronic control unit 5 as illustrated in Fig. 3.

The pre-processing circuitry 60 includes an input node 50, a low pass filter 54, a high pass filter 52, a first analogue to digital converter (ADC) 55, a second analogue to digital converter (ADC) 53 and an amplifier 52.

The low pass filter 54 and high pass filter 51 are connected in parallel to the input node 50. The low pass filter 54 is connected in series to the first ADC 55 and the high pass filter is connected in series to the amplifier 52 which is connected to the second ADC.

The low pass filter 54 converts the sensor output 41 into a signal (Idc) that represents the steady-state or slowly varying intensity of the light detected by the PPG sensor 4. This signal is sampled and digitised by the second ADC and then provided to the processor 56.

The high pass filter 51 converts the sensor output 41 into a signal (Iac) that represents the varying intensity of the light detected by the PPG sensor 4. This signal is amplified by amplifier 52 and it is then sampled and digitised by the second ADC and then provided to the processor 56.

The low pass filter passes signals with a frequency less than ~1Hz, whereas the high pass filter passes signals with a frequency of greater than ~1Hz. The high pass signal Iac is therefore representative of the change of intensity caused by arterial pulses in the lower limb 12 of the subject. These cut-off frequencies may have to adapt, in practice, to individual heart rates.

The processor 56 processes the digitised signals Idc and Iac. It calculates a ratio of ratios R,

$$R = \frac{I(\theta)_{AC} / I(\theta)_{DC}}{I(0)_{AC} / I(0)_{DC}}$$

where

$I(\theta)_{ac}$ represents the varying intensity of the light detected by the PPG sensor 4 when the lower limb is elevated with an incline of θ.

$I(\theta)_{dc}$ represents the steady state intensity of the light detected by the PPG sensor 4d when the lower limb is elevated with an incline of θ.

$I(0)_{ac}$ represents the varying intensity of the light detected by the PPG sensor 4 when the lower limb is elevated with an incline of 0 (zero).

$I(0)_{dc}$ represents the steady state intensity of the light detected by the PPG sensor 4 when the lower limb is elevated with an incline of 0 (zero)

R will be unity if the blood volume pulsations remain unchanged as a proportion of the total blood volume when the limb is elevated. The ratio R can be used to categorise the postural response of the circulation system in the lower limb and foot.

For example, it might be the case that as the lower limb 12 is raised in a healthy arterial system Iac remains approximately constant but changes significantly for an unhealthy arterial system.

The value R represents a first perfusion indicator and it may be displayed on display 58.

Fig. 4A illustrates the change in pulsatile perfusion for a healthy subject's leg when raised to 30 degrees. The subject was a 35 year old female. The Fig plots a trace of pulsatile perfusion i.e. I_{AC} / I_{DC} on the Y-axis against time in seconds on the X-axis. The subject's leg is raised from 0 degrees elevation to 30 degrees elevation for 30 seconds between t=50 and 80 seconds. The plot of Fig 4A may be displayed contemporaneously on the display 58.

Fig. 4B illustrates the envelope of the trace in Fig 4A. The plot of Fig 4B may be displayed contemporaneously on the display 58.

The ratio R may be calculated from the ratio of pulsatile perfusion ($I(\theta)_{ac}$ / $I(\theta)_{dc}$) when t=60 and pulsatile perfusion ($I(0)_{ac}$ / $I(0)_{dc}$) when t=45. That is the ratio of the pulsatile perfusion soon after, but not immediately after, the leg has been raised to the pulsatile perfusion just before the leg has been raised. The ratio R for this healthy subject is in the region of 2. This indicates increased perfusion when the leg is elevated.

Fig. 5A illustrates the change in pulsatile perfusion for an at-risk subject's leg when raised to 30 degrees. The subject was a 79 year old diabetic male. The Fig plots a trace of pulsatile perfusion i.e. I_{AC} / I_{DC} on the Y-axis against time in seconds on the X-axis. The subject's leg is raised from 0 degrees elevation to 30 degrees elevation for 30 seconds between t=50 and 80 seconds. The plot of Fig 5A may be displayed contemporaneously on the display 58.

Fig. 5B illustrates the envelope of the trace in Fig 5A. The plot of Fig 5B may be displayed contemporaneously on the display 58.

The ratio R may be calculated from the ratio of pulsatile perfusion ($I(\theta)_{ac}$ / $I(\theta)_{dc}$) when t=60 and pulsatile perfusion ($I(0)_{ac}$ / $I(0)_{dc}$) when t=45. That is the ratio of

the pulsatile perfusion soon after, but not immediately after, the leg has been raised to the pulsatile perfusion just before the leg has been raised. The ratio R for this at-risk subject is in the region of 1. This indicates no change in perfusion when the leg is elevated.

The value of R indicates that the subject is at-risk of developing circulatory complications in the foot. In extreme at-risk cases, the value of R may be less than 1.

A clinically determined threshold value T may be determined, such that when R for a particular subject is below the threshold, they are deemed at risk. This may be detected and displayed on the display 58. The extent of risk may also be calibrated against the difference between the threshold and calculated value of R and a quantitative or qualitative indication of the extent of risk may be displayed on the display 58.

The total output I of the PPG sensor 4 can be represented as Idc + Iac. The value of I is governed to a major extent by the blood volume illuminated and the skin absorption. The effect of skin absorption is removed by the ratio of ratios R. Because R is calculated, the actual light intensity used for a particular subject can vary according to what is required to obtain a well-resolved signal. This will be a function of many factors including skin type, thickness, anatomy, probe placement and probe coupling. Adjustment of the light intensity can be performed to optimise the signal acquisition with respect to the dynamic range of measurement.

The process of objective assessment of blood perfusion in a lower limb 12 of a subject involves the following steps. The subject rests in a supine position and an optically diffusive skin (ODS) 16 is placed over at least the subject's dorsum. The system 10 is then attached to the lower limb 12 using a strap. The approximate height of the subject is entered into the control unit 5 using the keyboard 57. The

control unit 5 via the inclinometer 14 registers the base position (i.e. horizontal) and gives green light to proceed via display 58. The lower limb 12 of the subject is slowly raised and then held for a few seconds. The perfusion indicators are calculated and displayed.

Although the PPG sensor 4 is illustrated in Fig. 2 as a non-contact sensor, in alternative embodiments the sensor 4 may be attached to the lower limb, for example, by using an elasticated strap to hold the sensor 4 and control unit 5 in position during the test. The skin 16 also serves as a disposable hygiene barrier, reducing contamination of the sensors and cross infection between subjects.

The system 10 illustrated in Figs 2 and 3, may be simply adapted to determined a second perfusion indicator dependent upon the blanching of the skin tone of the lower limb 12 when it is elevated. This second perfusion indicator may be calculate in addition to or as an alternative to the first perfusion indicator R.

For example, a discrete spectrometer can be used to analyse the light reflected from the lower limb 12, when it is in the non-elevated position and when it is in the elevated position. The spectrometer can give a quantitative value for the blanching that occurs on elevating the limb.

As another example, the foot may be illuminated using IR light and also red light. An IR sensor's output may be pre-processed as described with reference to Fig. 3 to produce $I_{dc}[IR]$, $I_{ac}[IR]$. A red light sensor's output may be pre-processed as described with reference to Fig. 3 to produce $I_{dc}[red]$, $I_{ac}[red]$. The processor 56 may calculate a ratio R' or R"

$$R'_{ac} = \left(I_{dc}[red](\theta) / \left(I_{dc}[IR](\theta) + I_{dc}[red](\theta) \right) \right) / \left(I_{dc}[red](0) / \left(I_{dc}[IR](0) + I_{dc}[red](0) \right) \right)$$

$$R'_{ac} = \left(I_{ac}[red](\theta) / \left(I_{ac}[IR](\theta) + I_{ac}[red](\theta) \right) \right) / \left(I_{ac}[red](0) / \left(I_{ac}[IR](0) + I_{ac}[red](0) \right) \right)$$

It should be appreciated that embodiments of the invention do not provide a diagnosis but provide an interim clinical indicator that will, for example, help in the assessment of the risks associated with a condition such as diabetes.

Although embodiments of the present invention have been described in the preceding paragraphs with reference to various examples, it should be appreciated that modifications to the examples given can be made without departing from the scope of the invention as claimed.

Whilst endeavouring in the foregoing specification to draw attention to those features of the invention believed to be of particular importance it should be understood that the Applicant claims protection in respect of any patentable feature or combination of features hereinbefore referred to and/or shown in the drawings whether or not particular emphasis has been placed thereon.

Claims

1. A system for assessing a subject's pedal blood circulation, comprising:
measurement means for measuring a parameter dependent upon the blood volume in the subject's foot at a raised elevation and

processing means for determining a quantitative blood perfusion indictor using the measured parameter.

2. A system as claimed in claim 1, wherein the measurement means is operable to measure the parameter when the foot is at a first elevation and to measure the parameter when the foot is at a second elevation and wherein the processing means determines the perfusion indictor using the first parameter measured at the first elevation and the first parameter measured at the second elevation.

3. A system as claimed in claim 2, wherein the first elevation is a non-elevated position.

4. A system as claimed in claim 2 or 3, wherein the processing means determines the perfusion indicator using the ratio of the first parameter measured at the first elevation to the first parameter measured at the second elevation.

5, A system as claimed in claim 1 wherein the parameter is indicative of the total blood volume of the foot.

6, A system as claimed in claim 1 wherein the parameter is indicative of the arterial blood volume of the foot.

7. A system as claimed in any preceding claim further comprising means for determining the extent of elevation of the foot.

8. A system as claimed in any preceding claim wherein the processing means automatically determines a quantitative blood perfusion indictor.

9. A system as claimed in any preceding claim wherein the measurement means comprises means for isolating a steady state value of the measured parameter and a variable value of the measured parameter.

10. A system as claimed in claim 9, wherein the processing means calculates the ratio of the variable value to the steady state value at the raised elevation.

11. A system as claimed in claim 2, wherein the measurement means comprises means for isolating a steady state value of the measured parameter and a variable value of the measured parameter and wherein the processing mans calculates a value equivalent to the ratio of the ratio of variable parameter value to steady state parameter value for the first elevation to the ratio of variable parameter value to steady state parameter value for the second elevation

12. A system as claimed in any preceding claim, wherein the measurement means comprises light sensing means and the parameter is the intensity of light reflected from the foot.

13. A system as claimed in claim 12, wherein the measurement means additionally comprises an illumination source of fixed intensity.

14. A method for assessing a subject's pedal blood circulation, comprising: measuring a parameter dependent upon the blood volume in the subject's foot at a raised elevation and

determining a quantitative blood perfusion indictor using the measured parameter.

15. A method as claimed in claim 14, comprising measuring the parameter when the foot is at a first elevation and measuring the parameter when the foot is at a second elevation.

16. A method as claimed in claim 14 or 15, comprising calculating the ratio of the measured parameter at a second elevation to the measured parameter at a first elevation.

17. A method as claimed in claim 14, 15 or 16, comprising calculating the ratio of a variable component of the measured parameter at a first elevation to the static component of the measured parameter at the first elevation.

18. A method as claimed in any one of claims 14 to 17, comprising calculating the ratio of the variable component of the measured parameter at a second elevation to the variable component of the measured parameter at a first elevation.

19. A method as claimed in any one of claims 14 or 18, wherein the foot at the first elevation is not elevated.

20. A method as claimed in any one of claims 14 or 18 wherein the measured parameter is the intensity of light reflected from the foot.

21. A system or method for assessing a subject's pedal blood circulation substantially as hereinbefore described with reference to and/or as shown in the accompanying drawings.

22. Any novel subject matter or combination including novel subject matter disclosed, whether or not within the scope of or relating to the same invention as the preceding claims.

ABSTRACT

A system or method for assessing a subject's pedal blood circulation

A system for assessing a subject's pedal blood circulation, comprising: measurement means for measuring a parameter dependent upon the blood volume in the subject's foot at a raised elevation and processing means for determining a quantitative blood perfusion indictor using the measured parameter.

Fig. 3

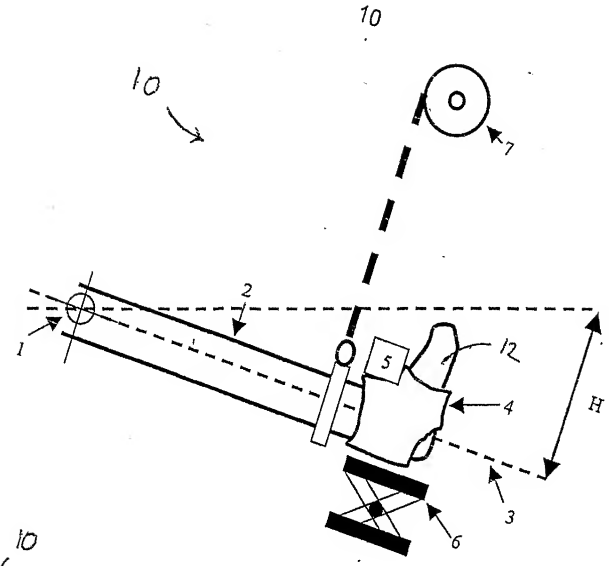

Fig. 1

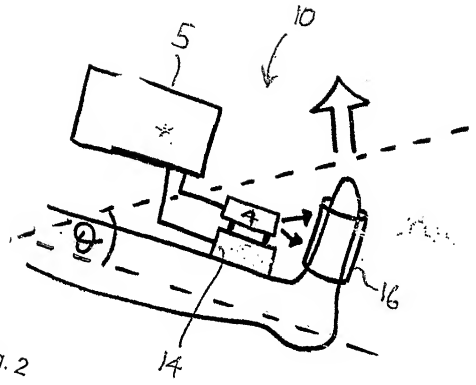

Fig. 2

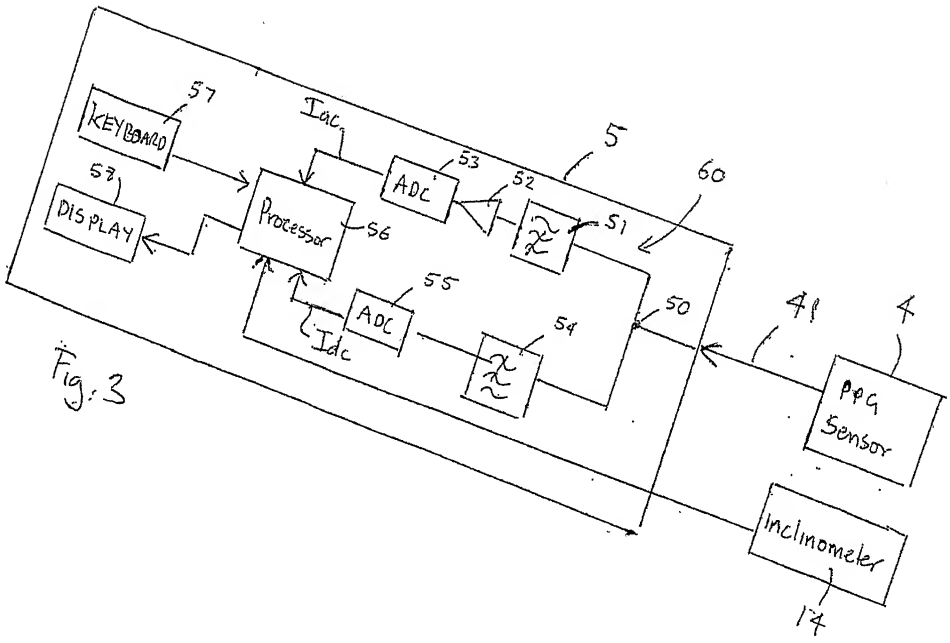

Fig. 3

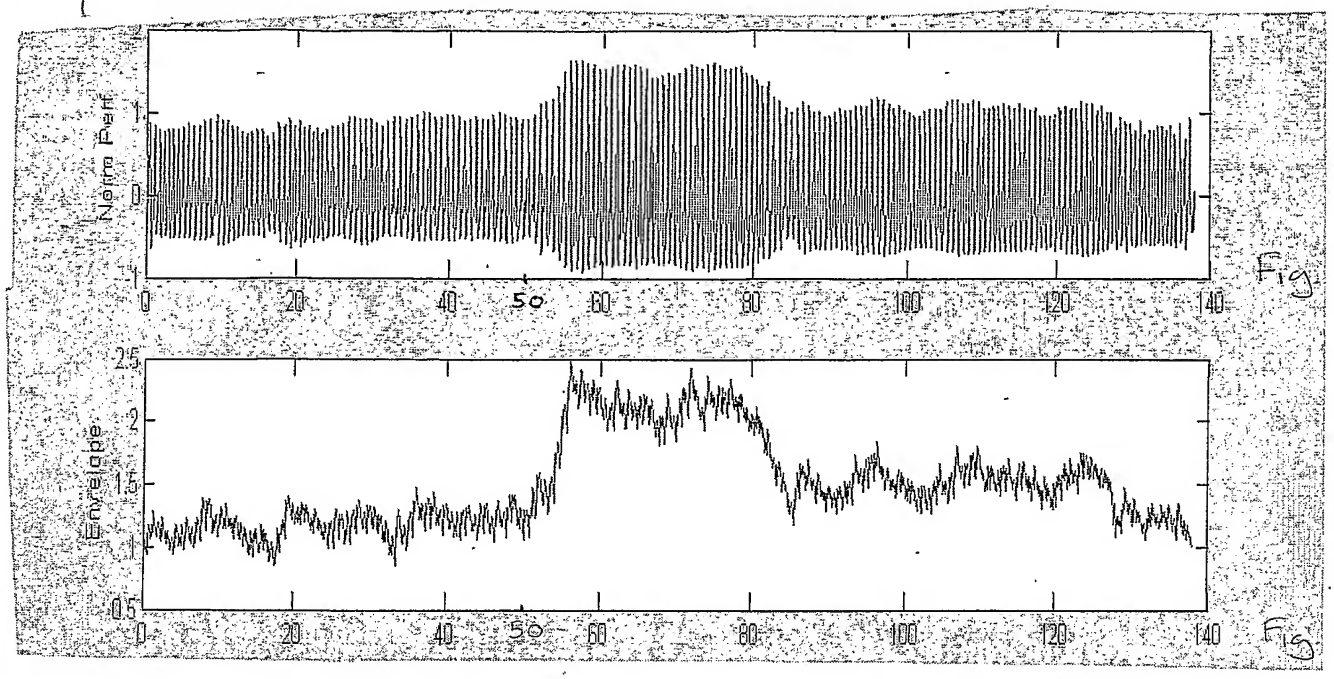

Fig 4A

Fig 4B

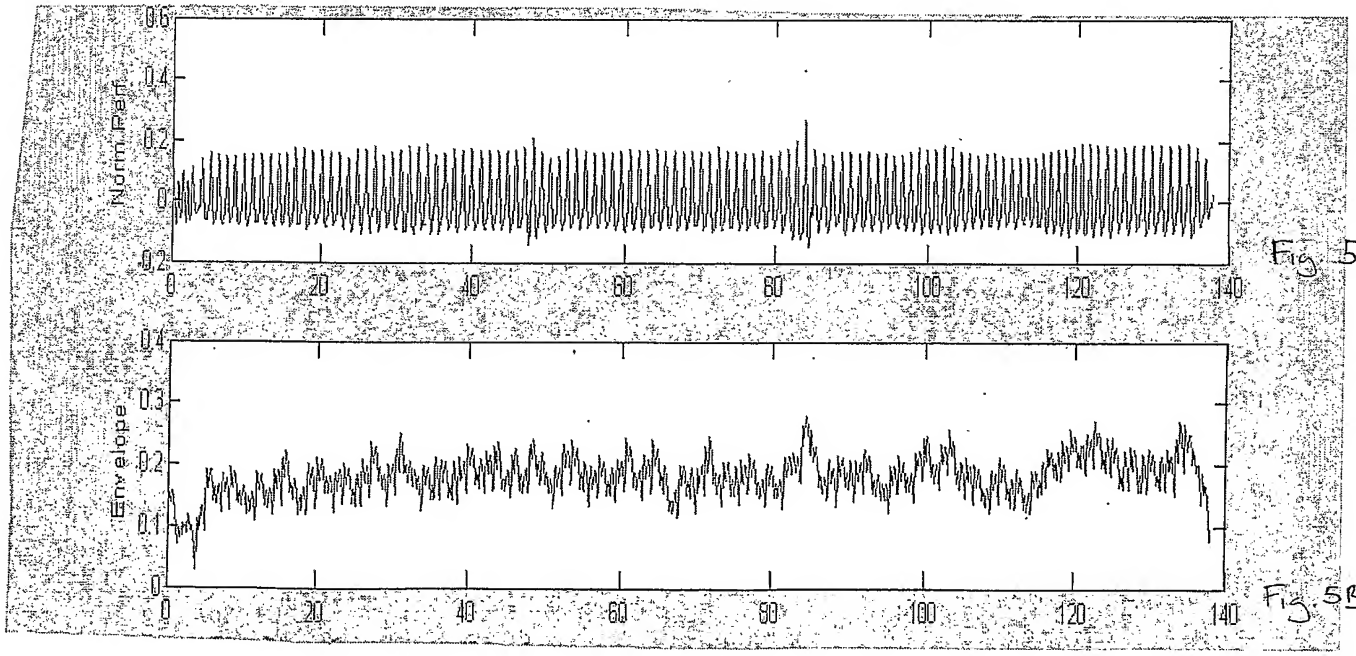

Fig 5A

Fig 5B